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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,008	07/23/2001	Franciscus Laurens Moll	08203.0014	1363
136.	7590	06/02/2004	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			LANDREM, KAMRIN R	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/910,008	<b>Applicant(s)</b> MOLL ET AL.	
	<b>Examiner</b> Kamrin R. Landrem	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5, 10-14, 17-21, 23-28 and 42-50 is/are pending in the application.
- 4a) Of the above claim(s) 20, 21, 23--28 and 47-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 10-14, 17-19 and 42-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/25/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Newly submitted claims 20,21,23-28 and 47-50 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: In paper No. 9 the applicant's representative elected Group I (a device for supporting vessels) without traverse. The new claims are directed towards method claims that were not previously elected for examination.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20,21,23-28 and 47-50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

\*\*\* Examiner's Note- Claim 27 has been withdrawn as being directed to a non-elected invention however the Examiner would like to point out that this claim depends from cancelled claim 22.

### ***Claim Objections***

Claim 19 is objected to because of the following informalities: Claim 19 depends from cancelled claim 6. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3738

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2,3,5,10,12,17,18,19, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Ryan et al (USPN 5,984,963).

With reference to Figures 13-16A Ryan discloses a device for internally supporting vessels having an outer wall and an inner wall that are both movable from a delivery configuration to expanded deployment configuration. With reference to Figure 15 Ryan discloses a first terminal portion 76 and a second terminal portion 78. The first terminal portion 76 comprises a guiding opening 82 (upper) and a female receiver/aperture 82 (lower) that is spaced apart from the guiding opening and capable of engaging with the male portion 80 of second terminal end 78. As shown in Figures 11B the first terminal end 76 overlaps the second terminal end 78 in a compressed configuration and Figure 11C shows the second terminal end 78 (male extensions 80) overlapping at least a part of the first terminal portion 76 after expansion (3:11-28). The inner and outer walls form one or more roughly circular elements and in Figures 18 and 19 one or more rings. The rings elements are interconnected by elements 89 and 98. The device may be radiopaque to allow it to be traceable when arranged in position within the body. Figures 4-6 disclose an assembly comprising a balloon and catheter 30 capable for delivering the device to or from a pre-desired location within the body (9:25-56). The stent may also serve as a medicament delivery system by comprising multiple layers of that include radiopaque film, drug releasing layers or other characteristics and combinations thereof (13:57-63).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11,13,14,43,44,45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan in view of Bates et al (USPN 6,530,951).

Ryan, as discussed above, discloses the device for internally supporting vessels as claimed. Ryan however fails to disclose that the device is made of a shape memory metal and specific multiple layer composition. Bates teaches a Nitinol (3:67) stent capable of delivering medicaments and radio-therapeutic agents (5:27-50) by way of a polymer (craft) or bioactive smooth film (tissue) layer to provide a device for reliably delivering suitable bioactive material during or flowing an intravascular procedure (7:35-47). Bates also teaches placing the coatings in particular amounts and positions to control the rate of release and the direction of release (15:15-16:58 and 6:27-65). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device disclosed by Ryan by manufacturing the device out of Nitinol and incorporated multiple layers to control release and reliably deliver medicaments after an intravascular surgery.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem  
Examiner  
AU 3738

krl



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**SUPERVISORY PATENT EXAMINER**  
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